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In the Supreme Court of the United States

OCTOBER TERM, 1966

No. 783

HENRY SCHEIN, D/B/A HENRY SCHEIN, PETITIONER

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

OPINION BELOW

The *per curiam* opinion of the court of appeals (Pet. App. B) is not yet reported. The opinion of the district court (Pet. App. C) is not reported.

JURISDICTION

The judgment of the court of appeals (Pet. App. D) was entered on October 21, 1966. The petition for a writ of certiorari was filed on November 18, 1966. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

QUESTIONS PRESENTED

1. Whether the trial court abused its discretion when it denied petitioner's post-sentence motion to withdraw his guilty plea.

2. Whether the trial court gave adequate and proper consideration to petitioner's sentence.

STATUTES AND REGULATIONS INVOLVED

21 U.S.C. 352(f)(1) defines a "misbranded" drug as one the label of which does not bear adequate directions for use, but authorizes the Secretary of Health, Education and Welfare to promulgate "regulations exempting such drug * * * from such requirement." The Secretary has promulgated the following pertinent regulations:

> 21 C.F.R. § 1.106 Drugs and devices, directions for use—
>
> * * * * *
>
> (b) *Exemption for prescription drugs.* A drug subject to the requirements of section 503(b)(1) of the act shall be exempt from section 502(f)(1) if all the following conditions are met:
>
> (1) The drug is:
>
> (i)(a) In the possession of a person (or his agents or employees) regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale distribution of prescription drugs; or
>
> (b) In the possession of a retail, hospital, or clinic pharmacy, or a public health agency, regularly and lawfully engaged in dispensing prescription drugs; or
>
> (c) In the possession of a practitioner licensed by law to administer or prescribe such drugs; and
>
> (ii) It is to be dispensed in accordance with section 503(b).
>
> * * * * *

(m) *Exemption for drugs and devices for use in teaching, law enforcement, research, and analysis.* A drug or device subject to paragraph (b), (c), or (d) of this section shall be exempt from section 502(f)(1) of the act if shipped or sold to, or in the possession of, persons regularly and lawfully engaged in instruction in pharmacy, chemistry, or medicine not involving clinical use, or engaged in law enforcement, or in research not involving clinical use, or in chemical analysis, or physical testing, and is to be used only for such instruction, law enforcement, research, analysis, or testing.

STATEMENT

On August 26, 1964, a sixteen-count information was filed in the United States District Court for the Eastern District of New York charging petitioner with violations of the Food, Drug, and Cosmetic Act. On September 24, 1964, petitioner, represented by counsel, entered a plea of not guilty to all counts. On January 21, 1966, petitioner withdrew his plea of not guilty and entered a plea of guilty to counts 3 and 4, which charged him with having introduced misbranded drugs into interstate commerce. On motion of the United States, the remaining counts were dismissed. On March 17, 1966, petitioner was fined $1000 on each count and sentenced to concurrent terms of imprisonment for two months. He later moved for a reduction of sentence. His motion was denied on May 3, 1966, after a full hearing at which he submitted a number of affidavits and exhibits. On May 12, 1966, petitioner, represented by different counsel, moved for leave to withdraw his guilty plea

and to dismiss counts 3 and 4 for failure to state an offense. The district court denied the motions and the court of appeals affirmed *per curiam*.

ARGUMENT

1. Four months after petitioner entered his plea of guilty, and two months after he was sentenced, petitioner—for the first time—moved to withdraw the plea. At that late stage of the proceedings the trial judge had of course a broad discretion in acting on the motion, particularly since no issue regarding petitioner's knowledge, understanding, or voluntariness in entering the plea was raised. *Kercheval* v. *United States,* 274 U.S. 220, 224; *Verdon* v. *United States,* 296 F. 2d 549 (C.A. 8), certiorari denied, 370 U.S. 945.[1] That discretion was not abused. In addition, the district court properly rejected petitioner's allegation that counts 3 and 4 failed to state an offense. These counts charged that on or about January 31, 1963, petitioner sent from Flushing, New York to Howard E. Pilson in San Francisco, California certain drugs that were misbranded in that their labeling failed to bear adequate directions for use, and that they were dispensed by petitioner without a prescription from a practitioner licensed by law to administer the drug. Pilson was a Food and Drug Inspector who

[1] It is apparent from the record (R. 10a–18a) that the motion to withdraw was motivated by petitioner's dissatisfaction with the imposition of a term of imprisonment. However, it is no ground for withdrawal of a guilty plea that petitioner did not anticipate a sentence as severe as the one imposed. *Verdon* v. *United States, supra; Friedman* v. *United States,* 200 F. 2d 690 (C.A. 8), certiorari denied, 345 U.S. 926.

posed as a physician when he placed the order for the drugs with petitioner's pharmaceutical company.

Petitioner's contention that these sales were exempt from the requirements of the Food and Drug Act by virtue of the regulations promulgated by the Secretary of Health, Education, and Welfare is without merit. He cites 21 C.F.R. 1.106(b)(1)(i)(a), exempting drugs "[i]n the possession of a person (or his agents or employees) regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale distribution of prescription drugs," and 21 C.F.R. 1.106(m), exempting drugs shipped to persons "regularly and lawfully engaged in instruction in pharmacy, chemistry, or medicine not involving clinical use, or engaged in law enforcement, or in research not involving clinical use, or in chemical analysis, or physical testing, and is to be used only for such instruction, law enforcement, research, analysis, or testing." Neither exemption is applicable. The Food and Drug Administration is not "regularly" engaged in the business of manufacturing, transporting, storing, or wholesale distribution of prescription drugs, and the exemption for "law enforcement" is clearly limited to shipments to the Food and Drug Administration for examinations and the like. Many successful prosecutions under the Food and Drug Act have involved shipments to federal agents posing as interested purchasers (see *United States* v. *Millpax, Inc.*, 313 F. 2d 152 (C.A. 7), certiorari denied, 373 U.S. 903; *Roth* v. *United States*, 270 F. 2d 655 (C.A. 8), certiorari denied, 361 U.S. 931; *De Freese* v. *United States*, 270 F. 2d 730 (C.A. 5), certiorari denied, 362

U.S. 944; *Brown* v. *United States*, 250 F. 2d 745 (C.A. 5), certiorari denied, 356 U.S. 938; *V. E. Irons, Inc.* v. *United States*, 244 F. 2d 34 (C.A. 1), certiorari denied, 354 U.S. 923), and the use of the federal decoy generally has long been countenanced (*Grimm* v. *United States*, 156 U.S. 604). There is no indication that the Secretary's regulations were intended to terminate this legitimate and indispensable law enforcement technique.[2]

2. The sentence imposed by the court was less than the statutory maximum, and the transcript of the sentencing hearing, read in its entirety, confirms the trial judge's own statement that his decision regarding the nature of the sentence imposed upon petitioner was not a "snap judgment" but "the result of very considerable study and analysis" (R. 18a). The judge noted that he had thoroughly studied petitioner's record and that he had obtained advice from his colleagues and from the Probation Bureau (R. 14a). The judge's reliance in part upon records that might not have been admissible at trial, and his refusal to reveal his sources of information to defense counsel, were not erroneous. See *Williams* v. *New York*, 337

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[2] Petitioner's other contentions are likewise without merit. The contention that the Act is violated only when the prohibited drug is distributed to the ultimate patient ignores the fact that Congress used the term "dispense" because it was broader than "sell." *Palmer* v. *United States*, 340 F. 2d 48, 50 (C.A. 5), certiorari denied, 382 U.S. 903. The contention that petitioner was merely following customary practice is answered in *Smith* v. *California*, 361 U.S. 147, 152, where this Court stated that in food and drug matters there is an "absolute standard [of care] which will not hear the distributor's plea as to the amount of care he had used."

U.S. 241; *Williams* v. *Oklahoma,* 358 U.S. 576; *Powers* v. *United States,* 325 F. 2d 666 (C.A. 1); *United States* v. *Durham,* 181 F. Supp. 503 (D.D.C.), certiorari denied, 364 U.S. 854.[3]

CONCLUSION

For the foregoing reasons, it is respectfully submitted that the petition for a writ of certiorari should be denied.

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DECEMBER 1966.

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[3] Rule 32(c) of the amended Rules of Criminal Procedure, effective July 1, 1966, provides:

> The court before imposing sentence *may* disclose to the defendant all or part of the material contained in the report of the presentence investigation and afford an opportunity to the defendant or his counsel to comment thereon. [Emphasis added.]

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